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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/066,285	02/01/2002	Greg Fahy	074066-0115	3778

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EXAMINER

SAUCIER, SANDRA E

ART UNIT	PAPER NUMBER
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1651

DATE MAILED: 09/26/2003

9

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application N .

10/066,285

Applicant(s)

FAHY ET AL.

Examiner

Sandra Saucier

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 01 August 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-6 and 36-66 is/are pending in the application.
- 4a) Of the above claim(s) 52-66 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-6 and 36-51 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 02 July 2002 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☒ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 12/13/02 . 6) ☐ Other: _____

DETAILED ACTION

Claims 1–6, 36–66 are pending. Claims 1–6, 36–51 are considered on the merits. Claims 52–66 are withdrawn from consideration as being drawn to a non-elected invention.

Election/Restriction

Claims 36–66 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention as elected in paper # 8 with traverse. The election of Group V, a composition comprising lactose, polyglycerol and glutathione is acknowledged.

The traverse is on the grounds that all the groups may be examined in the same search and without undue burden. The argument is not found persuasive because the method claims require a distinct composition from the elected composition claims. That is, the composition is directed to a combination of lactose, polyglycerol and glutathione. This is not the composition required by the method claims. The examination of multiple compositions and methods of use of multiple compositions does present a burden. It is highly unlikely that applicants would accept an anticipatory reference showing the use of lactose alone in a method of preserving cells as making the elected composition of lactose, polyglycerol and glutathione anticipated.

Upon the determination of an allowable composition, methods of use of that composition may be rejoined upon submission of claims by the applicant.

Oath/Declaration

A new oath or declaration is required because a part of the declaration has been lined through by the inventor GMF. It is unclear if the second inventor signed the amended declaration or the original wording. The wording of an oath or declaration cannot be amended. If the wording is not correct or if all of the required affirmations have not been made or if it has not been properly subscribed to, a new oath or declaration is required. The new oath or declaration must properly identify the application of which it is to form a part,

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preferably by application number and filing date in the body of the oath or declaration. See MPEP §§ 602.01 and 602.02.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-6, 36-51 are provisionally rejected under the judicially created doctrine of double patenting over claims 6, 18, 21 of copending Application No. 09/916396. This is a provisional double patenting rejection since the conflicting claims have not yet been patented.

The subject matter claimed in the instant application is fully disclosed in the referenced copending application and would be covered by any patent granted on that copending application since the referenced copending application and the instant application are claiming common subject matter, as follows: a solution comprising lactose and polyglycerol.

Claim Rejections – 35 USC § 112

INDEFINITE

Claims 2 and 51 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 2 refers to alpha lactose as a component of the mixture. However, the Merck Index [U] states that an equilibrium exists between the alpha and beta forms of lactose in a solution of milk. This means that in a solution, a certain equilibrium will be maintained depending on factors such as pH, temperature, etc.. It is not understood how in solution, lactose can be made to assume only the alpha form as in the claimed composition. This appears to be contrary to the scientific principle of equilibrium. Thus, the claim is indefinite. Please explain.

In claim 51, the recitation refers to “impermeant species”. The term “impermeant” with regard to compounds does not have a specific meaning in the art. Please note that the same compound, glucose, is said to be an impermeant chemical in US 6,194,137 (col. 6, l. 41) while in US 5,800,978 (col. 15, l. 34) it is said to be a “permeable compound”. Thus, the term, impermeant, is not indicative of any metes and bounds because the same compound can be said to be both a permeant and an impermeant.

Claim Rejections – 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action: (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1-4, 6 are rejected under 35 U.S.C. 103(a) as being unpatentable over US 6,616,858 [A] or Klebe *et al.* [U] in view of US 6,194,137 [B].

The claims are directed to a solution comprising lactose and polyglycerol for use as a preservation solution for cells, organs, tissues under hypothermic conditions.

The references are relied upon as explained below.

US 6,616,858 discloses that solutions comprising polyglycerol protect tissues and organs under hypothermic conditions.

Klebe *et al.* disclose that decaglycerol is a cryoprotective agent (Table 1).

US 6,194,137 discloses that lactose has cryoprotectant properties (col. 6, l. 41). Further, that any combination of cryoprotectants may be contained in a cryoprotectant solution (col. 6, l. 23).

The addition of a polyglycerol to the solution of US 6,194,137 would have been obvious when the disclosures of either Klebe *et al.* or US 6,616,858 were taken because Klebe *et al.* and US 6,616,858 both teach that polyglycerol is a

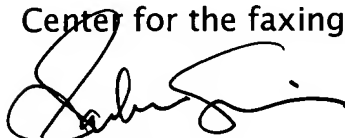
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cryoprotectant and US 6,194,137 states that any cryoprotectants may be components of the cryoprotective solution.

One of ordinary skill in the art would have been motivated at the time of invention to make this combination of compounds in order to obtain the resulting composition as suggested by the references with a reasonable expectation of success. The claimed subject matter fails to patentably distinguish over the state of the art as represented by the cited references. Therefore, the claims are properly rejected under 35 U.S.C. § 103.

To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to Group Art Unit 1651. The supervisor for 1651 is M. Wityshyn, (703) 308-4743. The normal work schedule for Examiner Saucier is 8:30 AM to 5:00 PM Monday and Tuesday and 8:30 AM to noon on Wednesday.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sandra Saucier whose telephone number is (703) 308-1084. Status inquiries must be directed to the Customer Service Desk at (703) 308-0197 or (703)-308-0198. The number of the Fax Center for the faxing of official papers is (703) 872-9306.



Sandra Saucier

Primary Examiner

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September 24, 2003